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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED and BAUSCH HEALTH AMERICAS INC., Plaintiffs, v. GLENMARK PHARMACEUTICALS LIMITED, Defendant.	Civil Action No 19-14502 *Document Electronically Filed*

COMPLAINT

This is a patent infringement action brought by Plaintiffs Bausch Health Ireland Limited ("Bausch Ireland") and Bausch Health Americas Inc. ("Bausch Americas") (collectively, "Bausch" or "Plaintiffs") for infringement of U.S. Patent No. 8,809,307 (the "'307 Patent") by Defendant Glenmark Pharmaceuticals Limited ("Glenmark" or "Defendant"), through the filing of Abbreviated New Drug Application ("ANDA") No. 213323 for the approval of Defendant's generic version of Plaintiffs' Bryhali™ product described therein. Plaintiffs hereby allege as follows:

THE PARTIES

1. Plaintiff Bausch Ireland is a private company incorporated in Ireland with its office located at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. Plaintiff Bausch Americas is a corporation organized and existing under the laws of Delaware. Its headquarters is located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

3. Upon information and belief, Glenmark is a corporation organized and existing under the laws of India with its principal place of business at Glenmark Pharmaceuticals Limited, B/2, Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai, India – 400 026.

4. On information and belief, Glenmark together with its subsidiaries develops, manufactures, and markets pharmaceutical products in India, the United States, Latin America, Europe, and internationally.

NATURE OF THE ACTION

5. This is a civil action for infringement of the ’307 Patent. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.

6. This action arises out of Glenmark filing ANDA No. 2213323 (“Glenmark ANDA”) including its “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging, *inter alia*, that the ’307 Patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the Glenmark ANDA Product (defined below).

JURISDICTION AND VENUE

7. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Glenmark by virtue of, *inter alia*, the fact that it has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in this District.

9. This Court has personal jurisdiction over Glenmark for the further reasons that, *inter alia*, Glenmark (1) has substantial, continuous, and systematic contacts with this State, (2) markets, sells, and/or distributes generic pharmaceutical drug products to residents of this State, (3) intentionally markets and sells generic pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

10. Upon information and belief Glenmark Generics Inc., USA ("GGI") (formerly known as Glenmark Pharmaceuticals Inc., USA), is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

11. Upon information and belief, GGI is the North American division of Glenmark Generics Ltd., which is a wholly-owned subsidiary of Glenmark.

12. Glenmark through its subsidiaries and various agents (for example GGI) offers generic pharmaceutical products for sale in New Jersey and elsewhere in the United States and earns revenue from the distribution and sale in New Jersey of its generic pharmaceutical products.

13. Upon information and belief, this Court has personal jurisdiction over Glenmark because, on information and belief, Glenmark will collaborate with GGI for the purposes of marketing and selling the Glenmark ANDA Product once approved by the FDA. Upon information and belief, Glenmark conducts business through and with GGI and Glenmark Generics

Ltd., its wholly-owned subsidiaries. Glenmark has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. Glenmark directly or through its affiliates and agents, such as GGI and Glenmark Generics Ltd., develops, formulates, synthesizes, manufactures, markets, imports, offers to sell, and/or sells pharmaceutical drug products, including the Glenmark ANDA Product, in New Jersey.

14. In the alternative, Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Glenmark pursuant to Federal Rule of Civil Procedure 4(k)(2) because Glenmark has extensive contacts with the United States, including but not limited to the above-described commercial contract, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Glenmark is consistent with the laws of the United States and the United States Constitution.

15. Venue is proper as to Glenmark because it is a foreign defendant and can be sued in any district.

THE PATENT-IN-SUIT

16. On August 19, 2014, the ’307 Patent entitled “Pharmaceutical Formulations Containing Corticosteroids for Topical Administration” was duly and legally issued. (A copy of the ’307 Patent is attached as Exhibit 1.)

17. The named inventors of the ’307 Patent are Arturo Angel and Gordon Dow.

18. The FDA’s Electronic Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) lists the expiration of the ’307 Patent as November 2, 2031.

19. Bausch Ireland is the assignee of the ’307 Patent.

ACTS GIVING RISE TO THIS ACTION

20. Bausch Americas holds the approved New Drug Application ("NDA") No. 209355 for Bryhali™ 0.01% strength.

21. Pursuant to 21 U.S.C. § 355(b)(1), the '307 Patent is listed in Orange Book for Bryhali™ (halobetasol propionate) Lotion, 0.01% strength.

22. On information and belief, Glenmark submitted the Glenmark ANDA (ANDA No. 213323) to the FDA seeking approval to engage in the commercial manufacture, use or sale of the halobetasol propionate 0.01% topical lotion, hereinafter referred to as the "Glenmark ANDA Product."

23. Plaintiffs received from Glenmark a letter, dated May 15, 2019, (the "Glenmark Notice Letter"), stating that Glenmark had included a certification in the Glenmark ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '307, Patent is invalid, or will not be infringed by the commercial manufacture, use, or sale of the Glenmark ANDA Product (the "Paragraph IV Certification.")

24. The Glenmark ANDA refers to and relies upon the Bryhali™ NDA and contains data that, according to Glenmark, demonstrate the bioequivalence of the Glenmark ANDA Product and Bryhali™.

25. This action was commenced by Plaintiffs within 45 days of the date of receipt of the Glenmark Notice Letter.

CLAIMS FOR RELIEF

COUNT I
(Infringement of the '307 Patent)

26. Plaintiffs reallege and incorporate by reference the allegations contained in the preceding paragraphs.

27. On information and belief, Glenmark has infringed at least one claim of the '307 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Glenmark ANDA, by which Glenmark seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of the Glenmark ANDA Product prior to the expiration of the '307 Patent.

28. Moreover, if Glenmark manufactures, uses, sells, offers for sale, or imports into the United States, the Glenmark ANDA Product, or induces or contributes to any such conduct, prior to the expiration of the '307 Patent, including any applicable exclusivities or extensions, Glenmark would further infringe (either literally or under the doctrine of equivalents) at least one claim of the '307 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

29. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Glenmark ANDA be a date that is not earlier than the expiration of the term of the '307 Patent, including any extension(s) granted by the U.S. Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. §§ 154 or 156, or any late expiration of exclusivity for the '307 Patent to which Plaintiffs are or become entitled.

30. Plaintiffs will be substantially and irreparably harmed if Glenmark is not enjoined from infringing the '307 Patent.

31. Plaintiffs have no adequate remedy at law.

32. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek relief as follows:

1. A judgment that Glenmark has infringed one or more valid claims of the '307 Patent by submitting or causing to be submitted the Glenmark ANDA to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Glenmark's ANDA Product before the expiration of the the '307 Patent;

2. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Glenmark, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling the Glenmark ANDA Product within the United States, or importing the Glenmark ANDA Product into the United States, prior to the expiration of the '307 Patent;

3. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Glenmark ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '307 Patent, including any extensions;

4. A judgment declaring and enjoining Glenmark, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling the Glenmark ANDA Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '307 Patent prior to their expiration, including any exclusivities or extensions to which Plaintiff is or becomes entitled;

5. That Plaintiffs be awarded damages for their costs, disbursements, expert witness fees, and attorneys' fees and costs incurred in prosecution this action, for an exceptional case pursuant to 35 U.S.C. § 285 and as otherwise provided by law; and

6. Such other and further relief as the Court deems just and appropriate.

Dated: June 28, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.
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CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: June 28, 2019
Newark, New Jersey

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